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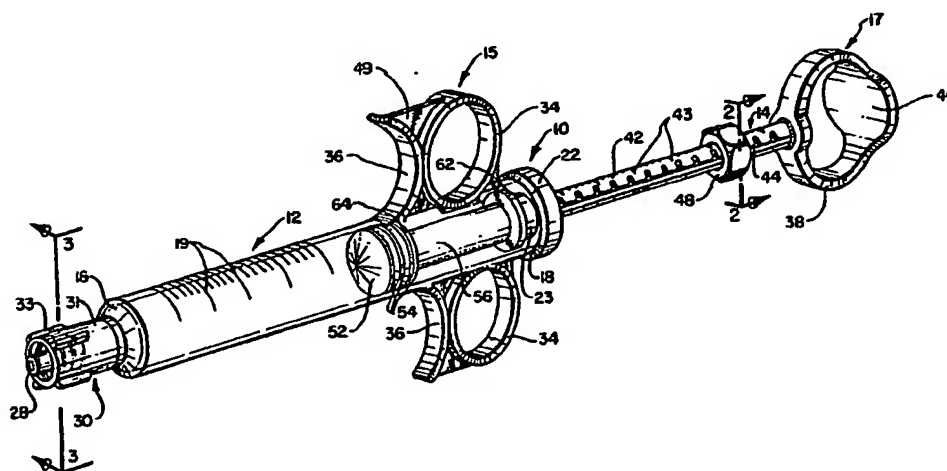
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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: DISPOSABLE CONTROL SYRINGE



(57) Abstract

A disposable medical control syringe (10) has a barrel (12) fabricated from a transparent plastic material and is provided with a pair of integral finger loops (34) and wing grips (36) to facilitate alternate ways of gripping and applying force to the syringe plunger (14). The plunger (14) has a resilient sealing tip (52) in slidable sealing engagement with the wall of the cylindrical bore of the barrel. First and second stabilizing disks (62, 64) are provided on the plunger to maintain the plunger in coaxial alignment as it is pushed through the barrel. A collar (56) on the plunger spaces the sealing tip (52) slightly forward of the finger loops (34) and wing grips (36). The plunger stem (42) is also provided with a thumb loop (38) having a palm rest (40) as well as a notched portion (44) arranged along its length. A locking nut (48) is provided which engages the notched portion to selectively limit the movement of the plunger into the bore. The leading end of the syringe barrel is connected to a medical device (such as a catheter manifold) by way of a rotatable luer lock connector (30) which is mounted on the body so it may be rotated independently of the body.

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DISPOSABLE CONTROL SYRINGEBACKGROUND

1

1. The Field of the Invention.

5 This invention relates to disposable medical syringes.  
More particularly, the present invention relates to a  
disposable control syringe.

10 2. The Background Art.

The customary hypodermic syringe and needle used to  
inject fluids into the human body is familiar to both medical  
professionals and the general public. However, syringes have  
15 many other uses in modern medicine besides intravenous or  
intramuscular injection of medication. For example, "control"  
syringes are known in the art, and are used for a variety of  
purposes. A control syringe capable of holding many  
20 milliliters of fluid (1 cc to 12 cc or more in contrast to the  
0.5 ml to 2 ml capacity of hypodermic syringes) must be  
capable of providing a relatively high pressure and rapid  
delivery of injectate. Further, the amount of injectate as  
25 well as the handling and manipulation of the syringe must be  
easily and precisely controllable.

For example, during angiographic procedures it is often  
30 necessary when using a control syringe to inject up to 12 cc  
of contrast media per injection. During angiographic  
injections, the flowing contrast media in the arteries or  
heart chambers is viewed under fluoroscopy. The injection of  
35 the contrast media allows the arteries and heart action, which

1 are not ordinarily visible on an X-ray film, to become  
observable. During angiographic procedures both the rate of  
injection and the amount of contrast media which is injected  
5 must be carefully controlled.

As another example of the need for control syringes,  
during procedures intended to measure cardiac output using  
thermodilution methods, a bolus of liquid colder than body  
10 temperature is injected into the heart by way of a catheter  
lumen. The change in temperature of the blood after it  
travels through the heart is then measured using a thermistor  
mounted on the end of the catheter. The amount of cold liquid  
15 injected into the catheter must be carefully controlled in  
order for the cardiac output to be measured accurately by the  
temperature change occurring in the blood.

As a further example, many catheterization procedures  
20 require that a balloon located somewhere along the length of  
the catheter be inflated with a liquid. In order to inflate  
the balloon, a syringe is filled with the liquid which is  
injected into the catheter lumen leading to the balloon.  
25 Importantly, the amount of fluid must be carefully controlled  
and must never exceed a predetermined amount or the  
possibility arises that the catheter balloon may rupture with  
30 potentially serious consequences.

Initially, control syringes which were used in the art  
were fabricated from stainless steel and glass. While these  
kinds of syringes provided a rugged, durable construction,  
35 they also suffered from the disadvantage that they were very

costly devices, they were difficult to manufacture, and there was always the attendant problem of having to sterilize the devices after use, with the further possibility of contamination if sterilization was not properly carried out. While the rugged and durable nature of these devices was certainly an advantage (particularly given the fact that control syringes are typically used in environments where significant pressure is often exerted on the plunger, even to the point where a physician will use two hands to push the plunger into the syringe barrel), the mentioned disadvantages represented significant drawbacks to this type of device.

With the improvement in biomedical materials and fabrication methods arising in connection with low-cost plastic medical devices, there has been a tendency to replace the steel and glass control syringes previously used in the art with syringes made from plastic materials which are inexpensive enough to be disposable. However, while these disposable control syringes have solved some of the problems which were experienced in connection with the glass and stainless steel syringes, such as elimination of the need for sterilization and reduction in cost of the device, the disposable syringes have, on the other hand, suffered a number of significant disadvantages of their own.

For example, many of the disposable control syringes which are in use today lack the rugged construction which is required to withstand the rigors inherent in many of the medical applications in which they are used. It is not

1 uncommon for such syringes to break at the point of connection  
where the syringe is attached to a device, such as a catheter  
manifold. Further, typical plungers of control syringes  
5 presently in use in the art lack the required rigidity and  
strength to withstand significant mechanical pressure when a  
physician uses one or even both hands to bear down on the  
plunger of the syringe when required to do so in order to  
10 inject the fluid. In such situations, it may not be uncommon  
for the syringe plunger to bend, which may result in binding,  
breakage or leaking of fluid out of the syringe barrel.

Still further, some disposable control syringes suffer  
15 from other design inadequacies such as partially occluding  
the plunger of the syringe so that the person using the  
syringe cannot view the entire length of the barrel which  
contains fluid to be injected. Visual inspection of the  
20 barrel is an important feature since one must ascertain that  
no air bubbles are present, otherwise the potential danger of  
injecting air into a vessel may be present.

25 Other design disadvantages which have been observed with  
some devices in use in the art include the inability to  
precisely control the amount of injectate which is to be  
infused from the syringe, as well as providing insufficient  
30 mechanical support on the syringe barrel and plunger to permit  
the necessary pressures to be applied in an easy and  
comfortable fashion. Still further, some control syringes in  
use in the art even allow the plunger to be inadvertently  
35



1 pulled out of the syringe barrel, which can a particularly  
aggravating occurrence when filling the syringe.

#### 5 BRIEF SUMMARY AND OBJECTS OF THE INVENTION

In view of the problems experienced with the previously  
available control syringes, it is an overall object of the  
present invention to provide a medical control syringe which  
10 may be fabricated using low cost materials and techniques so  
as to be disposable after a single use, but which is still  
rugged and durable enough to withstand the rigors required of  
such syringes.

15 More specifically, one object of the present invention  
is to provide a disposable control syringe wherein the plunger  
is designed so that bending is minimized throughout the  
plunger's movement through the syringe barrel, as well as  
20 assuring that the plunger's movement is smooth and does not  
bind.

Another object of the present invention is to provide a  
disposable control syringe wherein a locking mechanism is  
25 provided to preset and hence accurately control the maximum  
amount of fluid which can be injected, and which locking  
mechanism can be smoothly adjusted and easily snapped into  
30 place.

Still another object of the present invention is to  
provide a disposable control syringe which is provided with  
a structure which securely connects the syringe to a medical  
35 device such as a catheter manifold, which prevents breakage

1 or inadvertent disconnection, and which is sufficiently strong  
to still allow the syringe body to be rotated for easily  
orienting the syringe so that it can be conveniently grasped  
5 for use.

Yet another object of the present invention is to provide  
a disposable control syringe wherein a structure is provided  
so that the plunger is restrained to prevent its complete  
10 removal from the syringe barrel while filling the barrel.

Still another object of the invention is to provide a  
disposable control syringe wherein essentially the entire  
length of the barrel of the syringe which contains fluid to  
15 be injected is visible so as to permit visual inspection of  
the fluid being injected.

Still another important object of the present invention  
is to provide a disposable control syringe which is provided  
20 with appropriate structure for gripping the syringe so that  
application of the necessary force on the syringe plunger can  
be conveniently applied using any of several desired  
techniques, including application of force on the syringe  
25 plunger using two hands, or in the alternative, using one  
hand, and by application of the force using the thumb or the  
palm of the hand.

30 Additional objects and advantages of the invention will  
be apparent from the drawings, description and appended claims  
which follow, or may be learned by the practice of the  
invention.

35

1 Consistent with the foregoing objects, the present  
invention comprises a medical control syringe which provides  
the advantage of being of low enough cost to be disposable  
after a single use, while still incorporating the desirable  
5 features and advantages of a rugged, durable syringe that can  
withstand the rigors required in typical applications for such  
syringes, as explained above. The control syringe of the  
10 present invention comprises a barrel fabricated from a hard,  
polycarbonate plastic which is highly transparent to permit  
visual inspection of the fluid held within the syringe barrel.  
Both finger loops and wing grips are disposed on the sides of  
15 the barrel to allow the user to grasp the barrel in a variety  
of ways. A rigid, ABS plastic plunger is positioned within  
the syringe barrel. The leading end of the plunger is  
provided with a collar to space the tip of the plunger  
20 slightly forward of the grips, thus ensuring that injectate  
will always be forward of the point where the control syringe  
is grasped, and thus susceptible to visual inspection. A  
stabilizing disc on the collar and an end cap on the barrel  
25 cooperate to provide plunger stability so as to minimize  
bending of the plunger while it is being pushed through the  
barrel. The cap also prevents the plunger from being inadver-  
30 tently removed from the barrel when it is filled.

The plunger is provided with a releasable locking ring  
which may be preset to control the maximum amount of fluid  
which can be injected. A rotatable luer connector is provided  
35 on the barrel to connect the syringe to a medical device such

1 as a catheter manifold. The connector is preferably  
fabricated so that the body of the syringe may be rotated  
without loosening the connector or damaging the syringe while  
it is connected to the manifold, while still providing a  
5 mechanically stable attachment to the manifold. The plunger  
is also provided with a thumb loop having a palm rest to  
facilitate applying hand pressure using any of several  
10 alternative techniques.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of the presently preferred  
15 embodiment of the present invention.

Figure 2 is a cross-sectional view taken along line 2-2  
of Figure 1.

Figure 3 is an elevational cross-sectional view of the  
20 embodiment of Figure 1, showing the plunger fully retracted.

Figure 3A is an enlarged portion of Figure 3.

Figure 4 is an exploded perspective view of the  
embodiment of Figure 1.  
25

Figures 5A - 5C are perspective views which schematically  
illustrate alternative ways of grasping the control syringe  
of the present invention.

30

#### DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENT

Referring first to Figure 1, the control syringe of the  
present invention is generally designated at 10. The control  
35 syringe 10 is comprised of generally two main components. The

1 first is a barrel means for holding injectate which is to be  
expelled. In the illustrated embodiment the barrel means is  
comprised of a barrel assembly generally designated 12. The  
5 other main component of the control syringe is a plunger means  
which is slidably engaged within the barrel means. The  
plunger means is comprised of a plunger assembly generally  
designated at 14.

10 As shown best in Figure 3, the barrel assembly 12 is  
comprised of a cylindrical barrel 13 which has formed through  
the center of the barrel a bore 20. Preferably, the barrel  
13 is constructed from material that is highly visually  
15 transparent such as polycarbonate plastic or other material  
which is highly transparent and yet which is also preferably  
low cost. As hereinafter more fully explained, it is  
especially desirable that at least the leading end of the  
20 barrel 13 be sufficiently visually transparent as to permit  
inspection of the contents of the barrel. This provides the  
important safety feature that air bubbles will be readily  
ascertained so as not to be expelled into the patient when  
25 injecting the fluid from the syringe. In the illustrated  
embodiment of Figure 3, the visually transparent leading end  
of control syringe 10 is schematically represented by the  
30 distance "X" as shown at reference numeral 60.

With further reference to Figures 3 and 4, the barrel  
assembly 12 has at its forward end a conically shaped portion  
16 which terminates in a cylinder 35. At the base of cylinder  
35 35 there is a circular platform 47. The other end of cylinder

1 35 terminates in a smaller cylinder 39, over which a rubber  
O-ring 37 fits. O-ring 37 assures a fluid-tight seal between  
luer connector 30 and cylinder 35 onto which connector 30  
5 fits.

A rotatable female luer connector 30 with central  
cylindrical shaft 28 is provided with an extended base 31  
which snaps onto the cylinder 35. Bore 26 through the center  
10 of cylinders 35, 39 and shaft 28 provides a passageway through  
which injectate is expelled into a catheter manifold. A  
locking ring 45 on cylinder 35 is designed to mate with a  
corresponding groove formed on the inside surface of base 31.

15 The female luer connector 30 is adapted to rotate around  
cylinder 35 so as to provide a rotatable connector means for  
permitting rotation of the entire syringe when connected to  
a stationary device such as a manifold from which the fluid  
20 can be dispensed through appropriate catheter lines into a  
patient. By providing a rotatable connector means as  
described, the control syringe of the present invention can  
be quickly and easily oriented by rotating the syringe so that  
25 the physician can grasp the syringe in the most convenient  
manner thereby optimizing the application of force and  
facilitating more accurate control of the fluid as it is  
30 dispensed from the syringe.

Importantly, the cylinder 35 and platform 47 serve as a  
means for reinforcing and stabilizing the rotatable luer  
connector 30 when connected to a catheter manifold. Platform  
35 47 provides a flat, uniform support for base 31. Since the

1 end 16 of syringe barrel 13 is conical, without platform 47  
the base 31 of luer connector 30 would not have adequate  
support, permitting undesired movement at the point of  
connection between luer connector 30 and barrel 13. Cylinder  
5 35 further provides reinforcement between luer connector 30  
and the end of the syringe barrel 13. Base 31 of luer  
connector 30 and reinforcing cylinder 35 are designed to  
10 provide a good friction fit. Thus, syringe barrel 13 will be  
held in a desired position unless rotated in relation to luer  
connector 30. Rotatable female luer connector 30 is also  
preferably fabricated from polycarbonate plastic so as to  
15 provide sufficient rigidity and strength to resist breakage  
and/or inadvertent disconnection of the control syringe when  
connected to a device such as a catheter manifold.

With further reference to Figures 1 and 3, the barrel  
20 assembly 12 further comprises an end cap 22 which snaps onto  
a lip 19 at the trailing end 18 of the syringe barrel 13.  
The end cap 22 serves as a means for enclosing the trailing  
end of the syringe barrel 13, and is provided with a  
25 diametrically reduced collar 23 having an opening 24 through  
which the syringe plunger may slide back and forth when  
actuating the plunger.

30 A variable grip means is generally designated at  
reference numerals 15 and 17, and is designed to permit the  
syringe to be grasped by a physician in any one of several  
different manners. As shown in Figures 1 and 3, the variable  
35 grip means comprises, for example, a pair of wing grips 36 as

1 well as an adjacent pair of finger loops 34, and a thumb loop  
38 having a flattened palm member 40. Webbing 49 strengthens  
the grips 36 and loops 34. As shown best in Figures 5A - 5C,  
5 the variable grip means 15 and 17 permit either the wing grips  
36 to be used, or the finger loops 34 to be used, or a  
combination of the two when using both hands to apply force  
to the plunger, as well as providing for actuation of the  
10 plunger using the thumb or palm.

As shown in Figure 3, the syringe assembly generally  
designated 14 is comprised of an elongated stem 42. The stem  
has a notched portion provided along the length thereof, with  
15 the notches being illustrated as at reference numeral 44. A  
nut 48 is situated on the stem 42 and is used for limiting  
movement of the stem 42 when actuating the plunger such that  
a controlled amount of fluid can be expelled from the syringe  
20 depending upon placement of the nut 42 along the notched  
portion of the stem. Importantly, stem 42 is rounded and  
smooth so that it does not bind when moving through opening  
24 of collar 23 on the end cap 22. Furthermore, locking nut  
25 48 is designed so that a friction fit is provided when nut 48  
is on stem 42. This prevents nut 48 from sliding up and down  
on stem 42 and thus getting in the way when nut 48 is not in  
30 use.

The cross-sectional view of Figure 2 best illustrates the  
manner in which the nut 48 can be used as a means for limiting  
movement of the plunger to any of several selected positions  
35 relative to the syringe barrel. Locking nut 48 comprises a



1 protruding member 50 which extends inwardly so as to engage  
the notches 44 when the nut is rotated counter-clockwise in  
reference to the view of Figure 2. When the nut 48 is rotated  
clockwise in reference to Figure 2, the protruding member  
5 moves to the position illustrated at 51 (shown in dashed  
lines) so that the protruding member 50 slides along the slot  
46 which is formed adjacent the notched portion of stem 42.

10 Thus, by rotating the nut 48 so that the protruding  
member 50 engages slot 46, nut 48 can be moved to any desired  
position along the length of stem 42. The nut 48 can then be  
rotated as described above so that it snaps into and engages  
15 the selected notch at the desired position, thereby providing  
the means for limiting movement of the plunger when pushing  
the plunger through the syringe. Member 50, as seen best in  
Figure 3A, snaps into the notch, and is firmly held there by  
20 means of rounded protrusions 53 that are formed at the  
entrance to each notch.

Also provided along the notched portion are markings  
which correspond to the volume of fluid to be expelled from  
25 the syringe barrel. For example, the markings 43 on the  
notched portion can conveniently indicate the selected  
positions along the stem 42 which would fix the position of  
the locking nut 48 so as to permit, for example, increments  
30 of 1 cc, up to 12 cc, to be injected. Also, note that  
corresponding markings are provided on the barrel of the  
syringe as indicated at reference numeral 19. Barrel markings  
35 19 permit the amount of fluid to be injected into the patient

1 to be carefully monitored irrespective of whether the locking  
nut 48 is used to limit movement of the plunger or not.

5 The leading end of the plunger assembly 14 is comprised  
of a tip 52 which serves as a means for establishing a fluid-  
tight seal within the barrel such that the injectate or fluid  
within the barrel will not flow past the tip 52. The tip 52  
is preferably formed of a rubber-like material which will  
10 provide the needed fluid-tight fit while still permitting the  
plunger to slide freely back and forth inside the barrel. In  
the illustrated embodiment, as shown best in Figure 3, the  
rubber tip 52 fits over a disk 51 which is provided at the end  
15 of the plunger assembly 14.

At the end of the rubber tip 52 there is a second,  
diametrically enlarged disk 64. A cylindrical collar 56 extends  
from disk 64 at one end thereof to a disk 62 at the other end  
20 thereof. The collar 56 serves as a means for spacing the tip  
52 a selected maximum distance from the end cap 22 so that the  
tip 52 will be slightly forward of the wing grips 36 when the  
plunger assembly 14 is fully retracted and the barrel 13 is  
25 filled with injectate.

For example, as shown in Figure 3, when the plunger  
assembly 14 is fully retracted so as to permit the barrel of  
the syringe to be completely filled with injectate, note that  
30 the collar 56 serves to space the tip 52 a selected maximum  
distance which is indicated by the distance "Y" as designated  
at reference numeral 68 such that the tip 52 will be situated  
35 slightly forward of wing grips 36. Importantly, this assures

1 that the entire leading end 60 of syringe barrel 13 can be  
quickly visually inspected to make sure that there are no  
bubbles contained within the fluid to be injected into the  
patient.  
5

Furthermore, it will also be appreciated with reference  
to Figure 3 that the disks 64 and 62 are separated by a  
selected maximum distance which is illustrated by the distance  
10 "Z" as indicated at reference numeral 58 in Figure 3. By  
making sure that the disk 62 is spaced by this maximum  
distance Z from the tip 52 of the syringe plunger, the disk  
62 serves as a means for stabilizing the stem 42 of the  
15 plunger assembly as the plunger is pushed through the barrel  
of the syringe.

This stabilizing function results because the disk 62  
helps to impart increased rigidity to the stem 42 and helps  
20 to prevent bending of the stem 42 by engaging bore 20 and  
maintaining the stem 42 in coaxial alignment with the center  
of the syringe barrel as the plunger is pushed through the  
barrel. Further stability is provided by means of the collar  
25 23 (see Fig. 1) situated in the end cap 22.

Thus, as will be appreciated with reference to Figure 3,  
essentially three separate points of stability are provided  
30 by means of the structure of the plunger assembly, the three  
points being the disk 64, disk 62, and the collar 23 through  
which the stem 42 moves. In this manner, the two stabilizing  
disks 64, 62, as well as the support provided through the  
35 opening 24 of collar 23 all help to prevent bending so as to

1 maintain the syringe stem in coaxial alignment with the center  
of the syringe barrel as force is applied to the stem for  
purposes of dispensing the injectate or fluid contained in the  
5 syringe. Preferably, with the exception of cap 22, which is  
made of low-density polyethelene plastic, the entire plunger  
assembly 14 is fabricated from a hard plastic material such  
as ABS to provide further rigidity and strength to the overall  
10 assembly.

The exploded perspective view of Figure 4 serves to  
illustrate the preferred method of assembly of the control  
syringe. The locking nut 48 and end cap 22 are placed onto  
15 the stem 42, and collar 56 is then bonded onto the end of stem  
42. The rubber tip 52 is then placed over the end of disk 51  
and the plunger assembly is then inserted into the barrel 13  
of the syringe, and end cap 22 is shaped onto lip 19 of the  
20 syringe barrel 13. O-ring 37 is placed over cylinder 39, and  
then luer connector 30 is snapped onto reinforcing cylinder  
35 and secured by locking ring 45.

25 The present invention may be embodied in other specific  
forms without departing from its spirit or essential charac-  
teristics. The described embodiments are to be considered in  
all respects only as illustrative and not restrictive. The  
30 scope of the invention is, therefore, indicated by the  
appended claims rather than by the foregoing description.  
All changes which come within the meaning and range of  
equivalency of the claims are to be embraced within their  
35 scope.

1       What is claimed and desired to be secured by United  
States Letters Patent is:

5       1.   A medical control syringe for use in expelling an  
injectate in response to application of force applied by hand,  
said syringe comprising:

10       (a) barrel means for holding said injectate, said  
barrel means comprising:

      (1) a visually transparent leading end through  
which injectate is expelled;

15       (2) a trailing end comprising a cap means for  
enclosing said trailing end of said barrel means;  
and

      (3) grip means for grasping said barrel means  
when injecting said injectate; and

20       (b) plunger means slidably engaged within said  
barrel means and comprising:

25       (1) a leading end with a tip means for  
establishing a fluid-tight seal within said barrel  
means such that said injectate, when drawn into said  
barrel means, will not flow past said tip means;

30       (2) a trailing end projecting through said  
cap means so as to extend beyond the trailing end  
of said barrel means to permit application of force  
thereto by a user's hand so as to move said plunger  
means through said barrel means in response to said  
35       force; and

1                   (3) collar means disposed on said plunger  
means intermediate said leading and trailing ends  
of the plunger means, said collar means spacing said  
5                   tip means a selected maximum distance from said cap  
means so that said cap means will be slightly  
forward of said grip means when said plunger means  
is fully retracted and said barrel means is filled  
10                   with injectate, thereby assuring visual inspection  
of the entire amount of injectate to be expelled  
from said syringe.

15               2.    A syringe as defined in claim 1 further comprising  
rotatable connector means, disposed at said leading end of  
said barrel means, for permitting rotation of said syringe  
when connected to a manifold device.

20

                  3.    A syringe as defined in claim 2 wherein said  
connector means comprises a luer connector.

25

                  4.    A syringe as defined in claim 3 further comprising  
reinforcing and stabilizing means for connecting said luer  
connector to said leading end of the barrel means.

30

35

1        5. A syringe as defined in claim 4 wherein said  
reinforcing and stabilizing means comprises a platform formed  
at said leading end of said barrel means, said platform  
5 providing an essentially flat surface onto which said luer  
connector is seated, and said reinforcing and stabilizing  
means further comprising a cylinder over which said luer  
connector fits.

10

6. A syringe as defined in claim 5 wherein said  
reinforcing and stabilizing means further comprises an O-ring  
for providing a fluid-tight seal between said luer connector  
15 and said reinforcing cylinder over which said luer connector  
fits.

20        7. A syringe as defined in claim 1 further comprising  
lock means for limiting movement of said plunger means to any  
of several selected positions relative to said barrel means,  
whereby the amount of injectate expelled by movement of said  
25 plunger means is automatically controlled.

8. A syringe as defined in claim 7 wherein said lock  
means comprises a notched portion provided along the length  
30 of said plunger means intermediate said collar and said  
trailing end of the plunger means, and a lock nut for engaging  
said notched portion rearward of said cap means.

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1        9. A syringe as defined in claim 1 wherein said grip  
means comprises means for accommodating application of said  
hand force by any one of several different methods of  
application.  
5

10        10. A syringe as defined in claim 9 wherein said grip  
means comprises:  
a pair of finger loops disposed on said barrel  
means;  
a pair of wing grips disposed on said barrel means  
adjacent said finger loops; and  
15        a thumb loop disposed at said trailing end of the  
plunger means, said thumb loop comprising a flattened  
palm member.

20        11. A syringe as defined in claim 1 further comprising  
a stabilizing disc disposed on said collar means, said disc  
being separated by a selected maximum distance from said tip  
means, and cooperating with said cap means so as to provide  
25        in combination therewith a means for holding said plunger  
means essentially in coaxial alignment with the center of said  
barrel means as said plunger means is moved through the barrel  
30        means.

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12. A medical control syringe for use in expelling an  
injectate in response to application of force applied by hand,  
said syringe comprising:

an elongated cylindrical barrel comprising an  
interior bore therethrough and having a leading end  
through which injectate is expelled and a trailing end;

a cap means for enclosing said trailing end of said  
barrel;

an elongated generally cylindrical plunger coaxially  
aligned with said bore and comprising a leading end  
having a fluid-tight seal at the tip thereof, and a  
trailing end projecting through said cap so as to extend  
beyond the trailing end of said barrel to permit  
application of force thereto by a user's hand so as to  
move said plunger coaxially through said bore of the  
barrel in response to said force; and

a stabilizing disc disposed on said plunger  
intermediate said tip and said trailing end of the  
plunger, said stabilizing disc being separated from said  
tip by a selected maximum distance, said disc and said  
cap together providing a means for holding the plunger  
in essentially coaxial alignment within the center of  
said bore as the plunger is moved therethrough to expel  
said injectate, said stabilizing disc engaging an inside  
surface of said barrel defined by said bore.

1        13. A syringe as defined in claim 12 further comprising  
variable grip means for accommodating application of said hand  
force by any one of several different methods of application.

5        14. A syringe as defined in claim 13 further comprising  
a diametrically enlarged collar formed on said plunger behind  
said tip means, said collar having sufficient length such that  
10 when said plunger is completely withdrawn a trailing end of  
said collar will engage said cap so as to space said tip  
slightly forward of said grip means, and wherein said leading  
end of said barrel extends up to said grip means and is  
15 visually transparent, whereby the entire amount of injectate  
to be expelled from said syringe is susceptible to visual  
inspection.

20        15. A syringe as defined in claim 14 wherein said  
variable grip means comprises:

         a pair of finger loops disposed on said barrel;  
         a pair of wing grips disposed on said barrel  
25        adjacent said finger loops; and  
         a thumb loop disposed at the trailing end of said  
plunger, said thumb loop comprising a flattened palm  
30        member.

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1           16. A syringe as defined in claim 12 further comprising  
lock means for limiting movement of said plunger to any of  
several selected positions relative to said barrel, whereby  
5           the amount of injectate expelled by movement of said plunger  
is automatically controlled.

10           17. A syringe as defined in claim 16 wherein said lock  
means comprises a notched portion of said plunger along the  
length thereof intermediate said stabilizing disc and said  
trailing end of the plunger, and a slidable lock nut for  
15           engaging said notched portion intermediate said cap and said  
thumb loop.

          18. A syringe as defined in claim 12 further comprising  
20           rotatable connector means disposed at the leading end of said  
barrel for permitting rotation of said syringe when connected  
to a manifold device.

25           19. A syringe as defined in claim 12 further comprising  
reinforcing and stabilizing means for connecting said luer  
connector to said leading end of the barrel means.

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20. A syringe as defined in claim 19 wherein said reinforcing and stabilizing means comprises a platform formed at said leading end of said barrel means, said platform  
5 providing an essentially flat surface onto which said luer connector is seated, and said reinforcing and stabilizing means further comprising a cylinder over which said luer  
10 connector fits.

21. A syringe as defined in claim 20 wherein said reinforcing and stabilizing means further comprises an O-ring  
15 for providing a fluid-tight seal between said luer connector and said reinforcing cylinder over which said luer connector fits.

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22. A syringe as defined in claim 12 further comprising a second stabilizing collar disposed on said plunger intermediate said tip and said stabilizing collar that is  
25 separated from said tip by said selected maximum distance.

23. A medical control syringe for use in expelling an injectate in response to application of force applied by hand,  
30 said syringe comprising:

an elongated cylindrical barrel comprising an interior bore therethrough and having a visually transparent leading end through which injectate is  
35 expelled, and a trailing end;

1           a cap means for enclosing said trailing end of said  
barrel;

5           an elongated generally cylindrical plunger coaxially  
aligned with said bore and comprising a leading end  
having a fluid-tight seal at the tip thereof, and a  
trailing end projecting through said cap so as to extend  
beyond the trailing end of said barrel to permit  
10          application in force thereto by a user's hand so as to  
move said plunger coaxially through said bore of the  
barrel in response to said force;

15          variable grip means disposed on said barrel for  
accommodating application of said hand force by any one  
of several different methods of application;

20          a diametrically enlarged collar disposed on said  
plunger intermediate said tip and the trailing end of  
said plunger, said collar having sufficient length to  
space said tip a selected maximum distance from said cap  
means so as to be slightly forward of said grip means  
when the plunger is fully retracted into said barrel and  
25          the barrel is filled with injectate;

30          a stabilizing disc separated from said tip by a  
selected maximum distance and disposed on said collar,  
said disc and said cap together providing a means for  
holding the plunger in essentially coaxially alignment  
within the center of said bore as the plunger is moved  
therethrough to expel said injectate;

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1           rotatable connector means disposed at the leading  
end of said barrel for permitting rotation of said  
syringe when connected to a manifold device; and

5           lock means for limiting movement of said plunger to  
any of several selected positions relative to said  
barrel, whereby the amount of injectate expelled by  
movement of said plunger is automatically controlled.

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24. A medical control syringe for use in expelling an  
injectate in response to application of force applied by hand,  
said syringe comprising:

15           an essentially elongated, cylindrical, transparent  
barrel comprising a leading and a trailing end thereof,  
and having a bore therethrough;

20           a rotatable luer connector disposed at the leading  
end of said barrel;

25           a cap disposed at the trailing end of said barrel  
for enclosing the bore at the trailing end thereof, said  
cap having a diametrically reduced central bore  
therethrough which is coaxially aligned with the bore of  
said barrel;

30           an elongated, essentially cylindrical plunger  
comprising a leading end with a tip situated within said  
bore of the plunger, said tip comprising a means for  
forming a fluid-tight seal within said bore, and said  
plunger extending for a portion of the length thereof  
35           through said diametrically reduced bore of said cap;

1           variable grip means comprising:

          a pair of finger loops disposed on said barrel  
adjacent said cap;

5           a pair of wing grips disposed on said barrel  
adjacent said finger loops; and

          a thumb loop disposed at the trailing end of  
said plunger, said thumb loop comprising a flattened  
10          palm member;

          a diametrically enlarged collar disposed on said  
plunger immediately behind said tip, said collar having  
a sufficient length to space the tip slightly forward of  
15          said finger loops and wing grips when the plunger is  
fully withdrawn and the barrel is filled with injectate;

          first and second stabilizing discs disposed on said  
collar, said first stabilizing disc being spaced from  
20          said tip by a selected maximum distance such that said  
plunger is held in essentially coaxial alignment within  
the center of said bore of the barrel as the plunger is  
moved through the bore of said barrel, and said second  
25          stabilizing collar being positioned on said collar  
intermediate said first collar and said tip;

          said plunger having a notched portion of the length  
30          thereof which extends through the diametrically reduced  
bore of said cap; and

          a locking nut disposed on said notched portion of  
the plunger and movable so as to engage said cap at any  
35          one of several selected locations along said notched

1       portion of the plunger, whereby the amount of injectate  
expelled by said plunger is selectively varied by  
limiting movement of said plunger in relation to said cap  
5       when locked by said locking nut.

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## AMENDED CLAIMS

[received by the International Bureau on 18 August 1989 (18.08.89)  
original claims 1 - 24 replaced by amended claims 1 - 18 (7 pages)]

- 1        1.    A medical control syringe for use in expelling an  
injectate in response to application of force applied by  
hand, said syringe comprising:
- 5            (a)   barrel means for holding the injectate;
- (b)   cap means for enclosing one end of said  
barrel means;
- (c)   plunger means slidably engaged within said  
barrel means for expelling the injectate in response  
to the force applied by hand to said plunger means;
- 10          (d)   grip means for grasping said barrel means;
- (e)   tip means disposed on said plunger means for  
establishing a fluid-tight seal within said barrel  
means such that the injectate will not flow past said  
tip means;
- 15          (f)   collar means disposed on said plunger means  
for spacing said tip means slightly forward of said  
grip means when said plunger means is fully retracted  
and said barrel means is filled with injectate; and
- 20          (g)   stabilizing means, disposed on said plunger  
means intermediate said fluid-tight seal of said tip  
means and said cap means, for cooperating with said  
cap means so as to hold said plunger means in  
essentially coaxial alignment within the center of  
said barrel means as said plunger means is moved
- 25          therethrough to expel the injectate.
2.    A syringe as defined in claim 1 further  
comprising rotatable connector means for permitting  
rotation of said syringe when connected to a manifold
- 30          device.
3.    A syringe as defined in claim 2 further  
comprising reinforcing and stabilizing means for connecting  
said rotatable connector means to said means.

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4. A syringe as defined in claim 1 further comprising lock means for limiting movement of said plunger means to any of several selected positions relative to said  
5 barrel means, whereby the amount of injectate expelled by movement of said plunger means is automatically controlled.

5. A syringe as defined in claim 4 wherein said lock means comprises a notched portion provided along the length  
10 of said plunger means and a lock nut for engaging said notched portion rearward of said cap means.

6. A syringe as defined in claim 1 wherein said grip means comprises means for accommodating application of said  
15 hand force by any one of several different methods of application.

7. A syringe as defined in claim 6 wherein said grip means comprises:

20 a pair of finger loops disposed on said barrel means;

a pair of wing grips disposed on said barrel means adjacent said finger loops;

25 a thumb loop disposed on said plunger means, a portion of said thumb loop being flattened so as to form a palm member on said thumb loop.

8. A medical control syringe for use in expelling an injectate in response to application of force applied by  
30 hand, said syringe comprising:

an elongated cylindrical barrel comprising an interior bore therethrough and having a leading end through which injectate is expelled and a trailing end;

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1           a cap means for enclosing said trailing end of  
said barrel;

5           an elongated generally cylindrical plunger  
coaxially aligned with said bore and comprising a  
leading end having a fluid-tight seal at the tip  
thereof, and a trailing end projecting through said  
cap means so as to extend beyond the trailing end of  
said barrel to permit application of force thereto by  
a user's hand so as to move said plunger coaxially  
10 through said bore of the barrel in response to the  
force; and

15           a stabilizing means disposed on said plunger  
intermediate said fluid-tight seal of said tip and  
said trailing end of the plunger for cooperating with  
said cap means so as to hold said plunger in  
essentially coaxial alignment within the center of  
said bore as the plunger is moved therethrough to  
expel the injectate.

20           9. A syringe as defined in claim 8 further  
comprising variable grip means disposed on said barrel for  
accommodating application of the hand force by any one of  
several different methods of application.

25           10. A syringe as defined in claim 9 further  
comprising a diametrically enlarged collar formed on said  
plunger behind said tip, said collar having sufficient  
length such that when said plunger is completely withdrawn  
a trailing end of said collar will engage said cap means so  
30 as to space said tip slightly forward of said grip means,  
and wherein said leading end of said barrel extends up to  
said grip means and is visually transparent, whereby the  
entire amount of injectate to be expelled from said syringe  
is susceptible to visual inspection.

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11. A syringe as defined in claim 10 wherein said variable grip means comprises:

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a pair of finger loops disposed on said barrel means;

a pair of wing grips disposed on said barrel means adjacent said finger loops;

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a thumb loop disposed on said plunger means, a portion of said thumb loop being flattened so as to form a palm member on said thumb loop.

12. A syringe as defined in claim 8 further comprising lock means for limiting movement of said plunger to any of several selected positions relative to said barrel, whereby the amount of injectate expelled by movement of said plunger is automatically controlled.

13. A syringe as defined in claim 12 wherein said lock means comprises a notched portion of said plunger along the length thereof intermediate said stabilizing means and said trailing end of the plunger, and a slidable lock nut for engaging said notched portion intermediate said cap means and said thumb loop.

14. A syringe as defined in claim 8 further comprising rotatable connector means disposed at the leading end of said barrel for permitting rotation of said syringe when connected to a manifold device.

15. A syringe as defined in claim 8 further comprising reinforcing and stabilizing means for connecting said rotatable connector means to said leading end of the barrel means.

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1        16. A syringe as defined in claim 8 further  
comprising a second stabilizing means disposed on said  
plunger intermediate said tip and said diametrically enlarged  
collar.

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17. A medical control syringe for use in expelling an  
injectate in response to application of force applied by  
hand, said syringe comprising:

an elongated cylindrical barrel comprising an  
10 interior bore therethrough and having a visually  
transparent leading end through which injectate is  
expelled, and a trailing end;

a cap means for enclosing said trailing end of  
said barrel;

15 an elongated generally cylindrical plunger  
comprising a leading end having a tip means for  
forming a fluid-tight seal, and a trailing end  
projecting through said cap so as to extend beyond the  
trailing end of said barrel to permit application of  
20 the force thereto by a user's hand so as to move said  
plunger coaxially through said bore of the barrel in  
response to said force;

variable grip means disposed on said barrel for  
accommodating application of the hand force by any one  
25 of several different methods of application;

a diametrically enlarged collar disposed on said  
plunger intermediate said fluid-tight seal of said tip  
means and the trailing end of said plunger, said  
collar having sufficient length to space said tip  
30 means slightly forward of said grip means when the  
plunger is fully retracted into said barrel and the  
barrel is filled with injectate;

a stabilizing means, disposed on said plunger  
intermediate said fluid-tight seal of said tip means

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1 and said trailing end of the plunger, for cooperating  
with said cap means so as to hold said plunger in  
essentially coaxial alignment within the center of  
said bore as the plunger is moved therethrough to  
5 expel the injectate;

rotatable connector means disposed at the leading  
end of said barrel for permitting rotation of said  
syringe when connected to a manifold device; and

10 lock means for limiting movement of said plunger  
to any of several selected positions relative to said  
barrel, whereby the amount of injectate expelled by  
movement of said plunger is automatically controlled.

15 18. A medical control syringe for use in expelling an  
injectate in response to application of force applied by  
hand, said syringe comprising:

an essentially elongated, cylindrical,  
transparent barrel comprising a leading end and a  
20 trailing end thereof, and having a bore therethrough;

a luer connector disposed at the leading end of  
said barrel;

means for rotating said luer connector;

25 a cap disposed at the trailing end of said barrel  
for enclosing the bore at the trailing end thereof,  
said cap having a diametrically reduced central bore  
therethrough which is coaxially aligned with the bore  
of said barrel;

30 an elongated, essentially cylindrical plunger  
comprising a leading end with a tip situated within  
said bore of the plunger, said tip comprising a means  
for forming a fluid-tight seal within said bore, and  
said plunger extending for a portion of the length

1        thereof through said diametrically reduced bore of said cap;

         variable grip means comprising:

         a pair of finger loops disposed on said barrel  
5        means;

         a pair of wing grips disposed on said barrel means adjacent said finger loops;

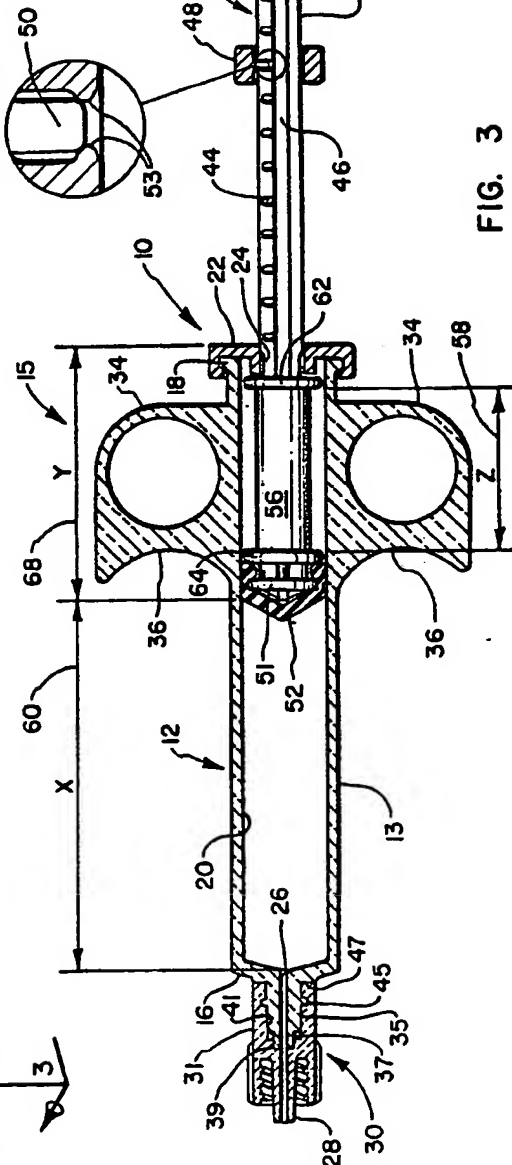
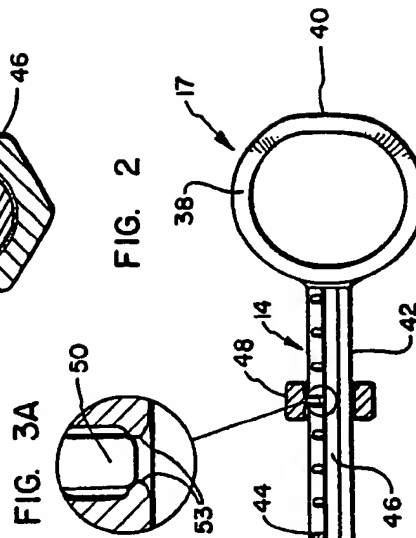
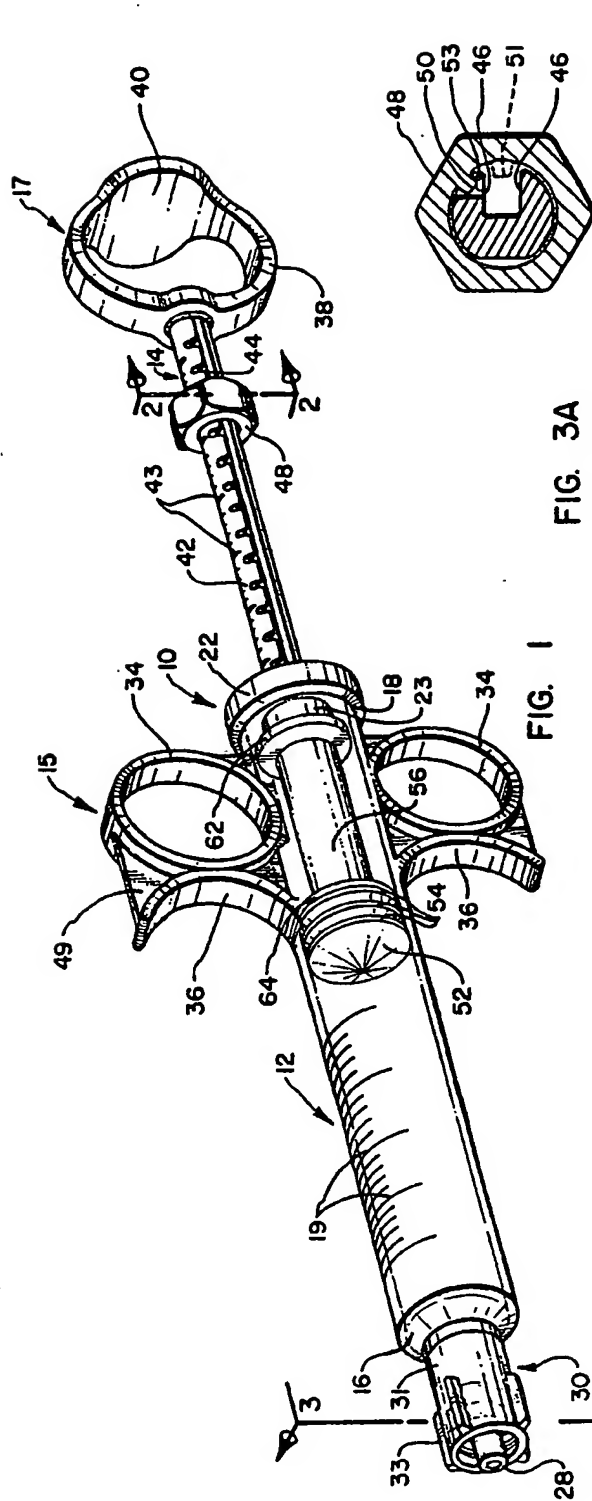
         a thumb loop disposed on said plunger means, a portion of said thumb loop being flattened so as to  
10       form a palm member on said thumb loop.

         a diametrically enlarged collar disposed on said plunger immediately behind said tip, said collar having a sufficient length to space the tip slightly forward of said finger loops and wing grips when the  
15       plunger is fully withdrawn and the barrel is filled with injectate;

         first and second stabilizing means spaced one from the other and disposed on said collar for stabilizing said plunger so that said plunger is held  
20       in essentially coaxial alignment within the center of said bore of the barrel as the plunger is moved through the bore of said barrel;

         said plunger having a notched portion of the length thereof which extends though the diametrically  
25       reduced bore of said cap; and

         a locking nut disposed on said notched portion of the plunger and movable so as to engage said cap at any one of several selected locations along said notched portion of the plunger, whereby the amount of  
30       injectate expelled by said plunger is selectively varied by limiting movement of said plunger in relation to said cap when locked by said locking nut.





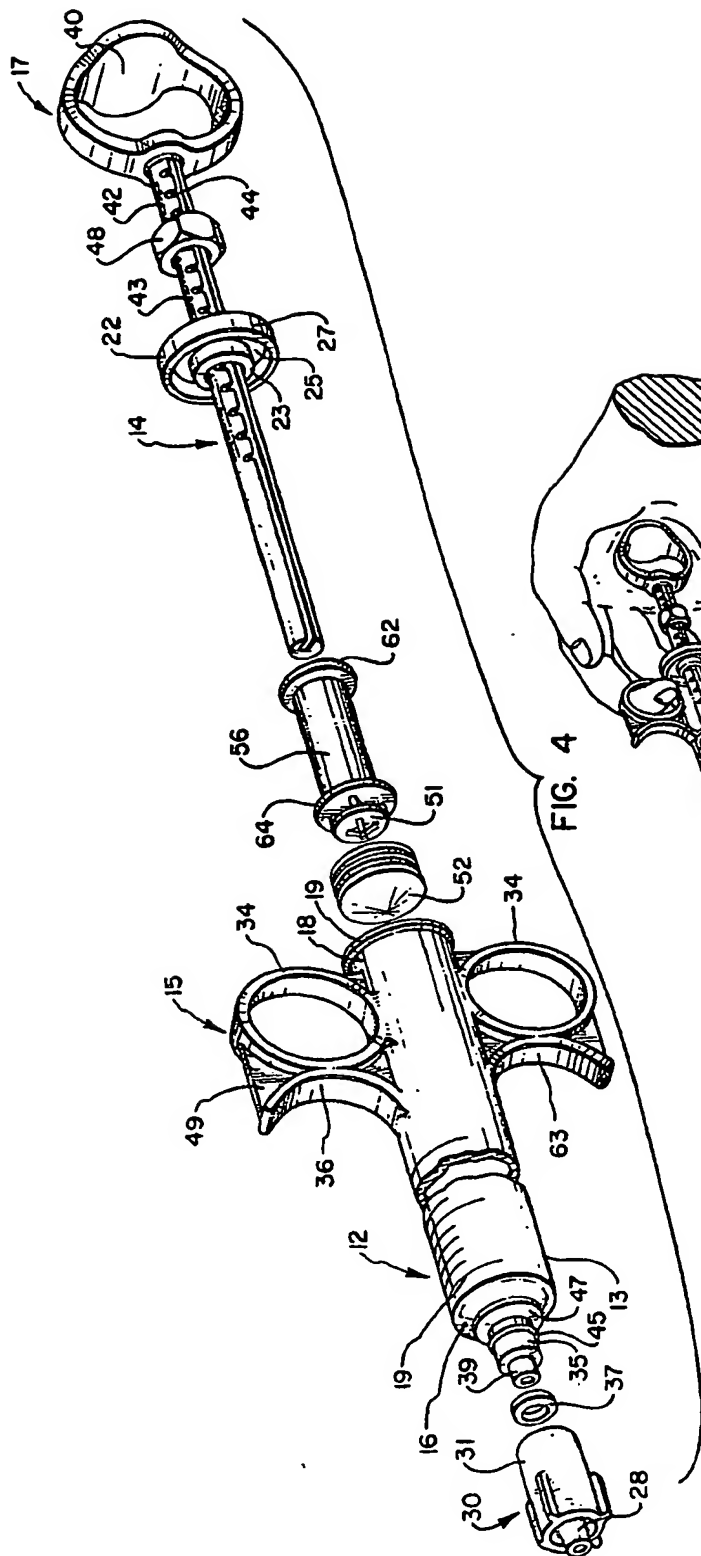


FIG. 4

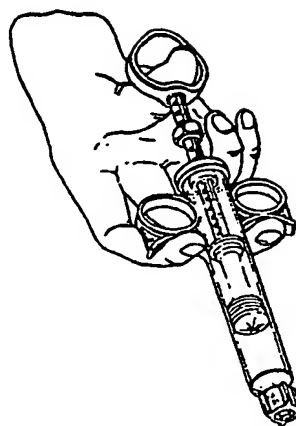


FIG. 5A

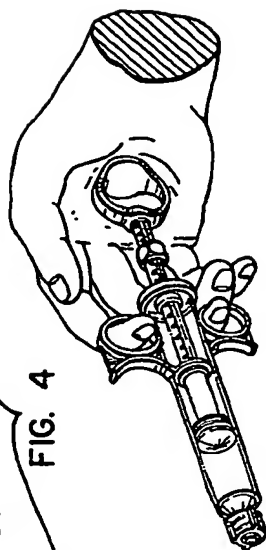


FIG. 5B

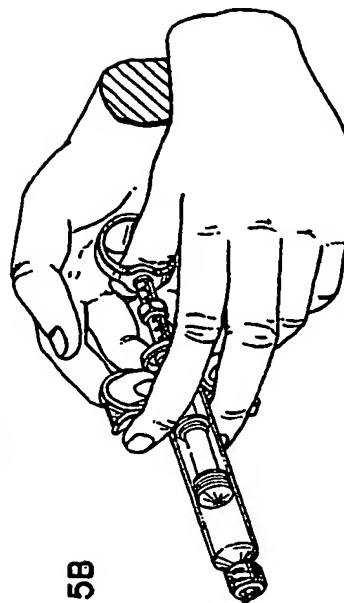


FIG. 5C

# INTERNATIONAL SEARCH REPORT

International Application No. **PCT/US89/00577**

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) <sup>6</sup>		
According to International Patent Classification (IPC) or to both National Classification and IPC <b>IPC (4): A61M 5/00</b> <b>U.S. C1: 604/187</b>		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched <sup>7</sup>		
Classification System	Classification Symbols	
U.S.	604/187, 208-211, 218, 222, 225, 227, 240-243	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched <sup>8</sup>		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT</b> <sup>9</sup>		
Category <sup>9</sup>	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>
Y	Product brochure of FMP for Control Ease Syringe, published prior to priority date although exact date unknown, see the entire document.	1-24
Y	Product brochure of COEUR Laboratories, Inc., published prior to priority date although exact date unknown, see the entire document.	1-11, 13-15, 23-24
Y	US, A, 2,656,836 (HICKEY) 27 October 1953 See the entire document.	2-6, 18-21, 23-24
Y	US, A, 3,491,757 (ARCE) 27 January 1970 See the entire document.	2-6, 18-21, 23-24
Y	US, A, 4,254,773 (WALDBILLIG) 10 March 1981 See the entire document.	2-6, 18-21, 23-24
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><sup>10</sup> Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&amp;" document member of the same patent family</p> </div> </div>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search		Date of Mailing of this International Search Report
26 April 1989		20 JUN 1989
International Searching Authority		Signature of Authorized Officer
ISA/US		K.M. Reichle